

Restriction Requirement Response
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Docket No. ORW01-GN005

In the Claims:

(ORIGINAL) 1. A system for assisting in a surgical process, comprising:
a surgical device taken from a group consisting of a surgical tool and a surgical implant;
a positional sensor carried by the surgical device, the positional sensor including a wireless transmitter and associated circuitry for transmitting sensor data from the transmitter; and
a computer system including a wireless receiver and signal conditioning circuitry and hardware for converting sensor data received by the wireless receiver into at least one of (a) audio feedback of positional information for the surgical device and (b) visual feedback of positional information for the surgical device.

(ORIGINAL) 2. The system of claim 1, further comprising a plurality of the positional sensors carried by the surgical device.

(ORIGINAL) 3. The system of claim 2, further comprising a reference sensor carried by a reference object, the reference sensor being operatively coupled to the signal conditioning circuitry and hardware so that reference sensor data is used in converting sensor data into visual feedback of positional information for the surgical device on a visual display.

(ORIGINAL) 4. The system of claim 1, wherein the surgical device is a surgical reamer adapted for use with a total hip arthroplasty procedure.

(ORIGINAL) 5. The system of claim 4, wherein the sensor data includes data regarding at least one of the position and orientation of the surgical reamer with respect to a patient's pelvic bone in several axes of movement.

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(ORIGINAL) 6. The system of claim 5, wherein the computer system is configured to convert the sensor into visual feedback on a visual display reflecting the position of the reamer with respect to the patient's pelvic bone.

(ORIGINAL) 7. The system of claim 5, wherein the computer system is operatively coupled to the reamer and is configured to control the reamer to reduce speed or stop upon the sensor data indicating that the reamer's position is outside of a predetermined range.

(WITHDRAWN) 8. The system of claim 5, wherein the sensor includes a magnetometer, and wherein the system includes a magnetic field generator for providing a reference magnetic field for the magnetometer.

(ORIGINAL) 9. The system of claim 8, wherein the magnetic field generator includes at least one magnet implanted about an acetabulum of the pelvic bone to provide a reference magnetic field for the magnetometer.

(ORIGINAL) 10. The system of claim 1, wherein the surgical device is one of a surgical drill and a hole-starter adapted for use with a total knee arthroplasty procedure.

(ORIGINAL) 11. The system of claim 10, wherein the sensor data includes data regarding at least one of the position and orientation of the surgical drill or hole-starter with respect to the patient's femur in several axes of movement.

(ORIGINAL) 12. The system of claim 11, wherein the computer system is configured to convert the sensor into visual feedback on a visual display reflecting the position of the surgical drill or hole-starter with respect to the patient's femur.

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(ORIGINAL) 13. The system of claim 11, wherein surgical device is a surgical drill, the computer system is operatively coupled to the surgical drill and is configured to control the surgical drill to reduce speed or stop upon the sensor data indicating that the drill's position is outside of a predetermined range.

(ORIGINAL) 14. The system of claim 11, wherein the sensor includes a magnetometer, and wherein the system includes a magnetic field generator providing a reference magnetic field for the magnetometer.

(ORIGINAL) 15. The system of claim 14, wherein the magnetic field generator includes at least one magnet implanted to the patient's femur to provide a reference magnetic field for the magnetometer.

(ORIGINAL) 16. The system of claim 1, wherein the surgical device is a surgical saw adapted for use with a total knee arthroplasty procedure.

(ORIGINAL) 17. The system of claim 16, wherein the sensor data includes data regarding at least one of the position and orientation of the surgical saw with respect to the patient's bone in several axes of movement.

(ORIGINAL) 18. The system of claim 17, wherein the computer system is configured to convert the sensor into visual feedback on a visual display reflecting the position of the surgical drill or hole-starter with respect to the patient's femur.

(ORIGINAL) 19. The system of claim 17, wherein the computer system is operatively coupled to the surgical saw and is configured to control the surgical saw to reduce speed or stop upon the sensor data indicating that the saw's position is outside of a predetermined range.

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(ORIGINAL) 20. The system of claim 17, wherein the sensor includes a magnetometer, and wherein the system includes a magnetic field generator providing a reference magnetic field for the magnetometer.

(ORIGINAL) 21. The system of claim 20, wherein the magnetic field generator includes at least one magnet implanted to the patient's bone to provide a reference magnetic field for the magnetometer.

(ORIGINAL) 22. The system of claim 17, further comprising a reference sensor carried by a reference object, the reference sensor being operatively coupled to the signal conditioning circuitry and hardware so that reference sensor data is used in converting sensor data into visual feedback of positional information for the surgical saw on a visual display

(WITHDRAWN) 23. The system of claim 17 wherein the reference object is a surgical jig adapted to be mounted to a distal end of the patient's femur.

(WITHDRAWN) 24. The system of claim 1, further comprising a reference sensor carried by a reference object, the reference sensor being operatively coupled to the signal conditioning circuitry and hardware so that reference sensor data is used in converting sensor data into at least one of (a) audio feedback of positional information for the surgical device with respect to the reference object and (b) visual feedback of positional information for the surgical device with respect to the reference object.

(WITHDRAWN) 25. The system of claim 24, wherein the reference object is a stem component adapted to be inserted into a canal of a patient's elongated bone.

(WITHDRAWN) 26. The system of claim 25, wherein the stem component is a trial stem.

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(WITHDRAWN) 27. The system of claim 24, wherein:

the surgical device is one of a tibial tray prosthetic device and a femoral prosthetic device of a prosthetic knee; and

the reference object is the other one of the tibial tray prosthetic device and the femoral prosthetic device.

(WITHDRAWN) 28. The system of claim 24, wherein:

the surgical device is one of a screw cap dome screw and an acetabular cup of a prosthetic hip; and

the reference object is the other one of the screw cap dome screw and the acetabular cup of the prosthetic hip.

(WITHDRAWN) 29. The system of claim 24, wherein:

the surgical device is surgical saw; and

the reference object a jig mounted to a patient's bone.

(WITHDRAWN) 30. The system of claim 24, wherein the reference object is one of a trial stem and a stem implant positioned within a canal of a patient's elongated bone.

(WITHDRAWN) 31. The system of claim 30, wherein the surgical device is one of a surgical saw, a surgical drill, a hole-starter and a prosthetic implant.

(WITHDRAWN) 32. The system of claim 29, wherein:

the reference object is one of a prosthetic implant and a prosthetic trial component; and

the surgical device is surgical instrument adapted perform at least one of the tasks consisting of inserting the reference object, extracting the reference object, positioning the reference object and impacting the reference object.

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(WITHDRAWN) 33. The system of claim 32, reference object is a prosthetic femoral stem component and the surgical instrument is a stem inserter.

(WITHDRAWN) 34. The system of claim 1, wherein the sensor includes a microgyroscope.

(WITHDRAWN) 35. The system of claim 1, wherein the sensor includes an accelerometer.

(ORIGINAL) 36. The system of claim 1, wherein the sensor includes an inclinometer.

(WITHDRAWN) 37. The system of claim 1, wherein the surgical device is a surgical cup inserter.

(WITHDRAWN) 38. The system of claim 37, further comprising one or more reference sensors mounted approximate a patient's acetabulum, the reference sensor being operatively coupled to the signal conditioning circuitry and hardware so that reference sensor data is used in converting sensor data into at least one of (a) audio feedback of positional information for the cup inserter with respect to the patient's acetabulum and (b) visual feedback of positional information for the cup inserter with respect to the patient's acetabulum.

(WITHDRAWN) 39. The system of claim 1, wherein the surgical device is a prosthetic trial component.

(WITHDRAWN) 40. The system of claim 39, further comprising a prosthetic implant component associated with the prosthetic trial component, wherein:

the computer system is configured to record positional information of the sensor when positioned within a patient's bone; and

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the computer system is further configured to utilize the recorded positional information of the sensor to guide the prosthetic implant, having an associated sensor, within the patient's bone.

(WITHDRAWN) 41. The system of claim 1, wherein the surgical device is a tibial tray prosthetic device.

(WITHDRAWN) 42. The system of claim 1, wherein the surgical device is an acetabular cup of a prosthetic hip.

(WITHDRAWN) 43. The system of claim 42, comprising a plurality of the sensors mounted about a rim of the acetabular cup.

(WITHDRAWN) 44. The system of claim 43, further comprising one or more reference sensors mounted approximate a patient's acetabulum, the reference sensor being operatively coupled to the signal conditioning circuitry and hardware so that reference sensor data is used in converting sensor data into at least one of (a) audio feedback of positional information for the acetabular cup with respect to the patient's acetabulum and (b) visual feedback of positional information for the acetabular cup with respect to the patient's acetabulum.

(WITHDRAWN) 45. The system of claim 1, wherein the surgical device is a femoral broach component.

(WITHDRAWN) 46. The system of claim 45, further comprising one or more reference sensors mounted approximate a patient's femoral canal, the reference sensor being operatively coupled to the signal conditioning circuitry and hardware so that reference sensor data is used in converting sensor data into at least one of (a) audio feedback of positional information for the femoral broach component with respect to the

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patient's femoral canal and (b) visual feedback of positional information for the femoral broach component with respect to the patient's femoral canal.

(ORIGINAL) 47. A system for assisting in a surgical process, comprising:
a surgical device taken from a group consisting of a surgical tool, a prosthetic component, and a surgical implant;
a sensor carried by the surgical device, the sensor operatively coupled to a wireless transmitter and associated circuitry for transmitting sensor data including at least one of positional data and orientational data outputted from the sensor; and
a computer system including a visual display, a wireless receiver, and signal conditioning circuitry and hardware for converting the sensor data received by the wireless receiver into visual feedback information for viewing on the visual display.

(ORIGINAL) 48. The system of claim 47, further comprising a plurality of sensors carried by the surgical device.

(WITHDRAWN) 49. The system of claim 48, further comprising a reference sensor carried by a reference object, the reference sensor adapted to be operatively coupled to the signal conditioning circuitry and hardware for converting the reference sensor data into visual reference feedback information concurrently displayable with the visual feedback information on the visual display.

(ORIGINAL) 50. The system of claim 47, wherein the sensor includes at least one of an accelerometer, a magnetometer, a gyroscope, an inclinometer, and a piezoelectric sensor.

(ORIGINAL) 51. The system of claim 47, wherein the surgical tool includes at least one of a surgical saw, a surgical drill, an intramedullary hole starter, a surgical hammer, a surgical reamer, and a surgical screwdriver.

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(ORIGINAL) 52. A surgical telemetry system comprising:

a sensor mounted to a surgical device, the sensor taken from the group consisting of an accelerometer, a magnetometer, a gyroscope, or an inclinometer;

a digital processing device operatively coupled to the sensor to receive data derived from data output from the sensor, the digital processing device generating a display output; and

a display operatively coupled to the digital processing device and adapted to receive the display output, where the display output displays the change in at least one of position and orientation of the sensor with respect to a point of reference.

(WITHDRAWN) 53. The surgical telemetry system of claim 52, wherein

the surgical device includes at least one of a cup inserter, a cup alignment instrument, a femoral component broach, a guide-rod of an intramedullary femoral and tibial cutting jig, an extramedullary femoral and tibial cutting jig, a screw cap dome, a prosthetic knee tibial tray, a prosthetic knee trial stem, a prosthetic knee trial tibial tray, a prosthetic knee femoral component, a prosthetic knee trial femoral component, a prosthetic hip femoral component, and a prosthetic hip trial femoral component.

(ORIGINAL) 54. The surgical telemetry system of claim 53, wherein the sensor is mounted within the surgical device.

(ORIGINAL) 55. The surgical telemetry system of claim 53, wherein:

the sensor is operatively coupled to a remote transmitter adapted to transmit signals indicative of sensor output as at least one of orientation and position of the sensor changes; and

the digital processing device is operatively coupled to a receiver adapted to receive transmission signals from the remote transmitter;

wherein the digital processing device generates display instructions for displaying at least one of the orientation and position of the sensor.

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(ORIGINAL) 56. The surgical telemetry system of claim 55, wherein the processing device is programmed to output display instructions including the relative dimensions of the surgical device, where the output display correlates the position of the sensor with respect to at least one of the orientation and position of the surgical device.

(ORIGINAL) 57. The surgical telemetry system of claim 55, wherein the display is adapted to display the relative dimensions of the surgical device, where the display correlates the position of the sensor with respect to at least one of the orientation and position of the surgical device.

(ORIGINAL) 58. The surgical telemetry system of claim 52, wherein the system is adapted for use with total knee arthroplasty.

(ORIGINAL) 59. The surgical telemetry system of claim 52, wherein the system is adapted for use with total hip arthroplasty.

(ORIGINAL) 60. The surgical telemetry system of claim 52, wherein the surgical device includes at least one of a surgical saw, a surgical drill, a surgical hammer, a surgical reamer, and a surgical screwdriver.

(ORIGINAL) 61. The surgical telemetry system of claim 60, wherein the sensor is mounted within the surgical device.

(ORIGINAL) 62. The surgical telemetry system of claim 61, wherein the surgical device includes a plurality of sensors mounted thereto.

(ORIGINAL) 63. The surgical telemetry system of claim 62, wherein the surgical device includes a plurality of sensors mounted thereto, where the plurality of sensors are taken from the group consisting of an accelerometer, a magnetometer, a gyroscope, or an inclinometer.

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(ORIGINAL) 64. A surgical telemetry system comprising:
a computer system having signal conditioning hardware and software;
a surgical instrument having an instrument positional sensor carried thereon, the instrument positional sensor being operatively coupled to the signal conditioning hardware and software of the computer system to transmit instrument positional data thereto; and
a prosthetic component having a prosthetic component positional sensor carried thereon, the prosthetic component positional sensor being operatively coupled to the signal conditioning hardware and software of the computer system to transmit prosthetic component positional data thereto.

(ORIGINAL) 65. The surgical telemetry system of claim 64, wherein the computer system is configured to process the instrument positional data and the prosthetic component positional data to generate relative position data indicative of the relative position of the surgical instrument with respect to the prosthetic component.

(ORIGINAL) 66. The surgical telemetry system of claim 65, wherein the computer system is further configured to generate at least one of audio and visual feedback of the relative position data.

(ORIGINAL) 67. The surgical telemetry system of claim 66, wherein:
the surgical instrument is taken from a group consisting of an insertion device, an extraction device, an impacting device, a positioning device, a surgical reamer, a surgical saw, a cutting jig, a surgical drill, a hole-starter, a surgical screw, a surgical bolt, a surgical screw-driver, a surgical bolt-driver and a material applicator; and
the prosthetic component is taken from a group consisting of a femoral stem; a femoral stem trial; an acetabular cup; an acetabular cup trial; a rod for insertion within a patient's bone cavity; and a prosthetic knee component.

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(ORIGINAL) 68. The surgical telemetry system of claim 64, wherein:

the surgical instrument is taken from a group consisting of an insertion device, an extraction device, an impacting device, a positioning device, a surgical reamer, a surgical saw, a cutting jig, a surgical drill, a hole-starter, a surgical screw, a surgical bolt, a surgical screw-driver, a surgical bolt-driver and a material applicator; and

the prosthetic component is taken from a group consisting of a femoral stem; a femoral stem trial; an acetabular cup; an acetabular cup trial; a rod for insertion within a patient's bone cavity; and a prosthetic knee component.

(ORIGINAL) 69. A surgical telemetry system comprising:

a computer system having signal conditioning hardware and software;

a first surgical instrument having a first instrument positional sensor carried thereon, the first instrument positional sensor being operatively coupled to the signal conditioning hardware and software of the computer system to transmit first instrument positional data thereto; and

a second surgical instrument having a second instrument positional sensor carried thereon, the second instrument positional sensor being operatively coupled to the signal conditioning hardware and software of the computer system to transmit second instrument positional data thereto.

(ORIGINAL) 70. The surgical telemetry system of claim 69, wherein the computer system is configured to process the first instrument positional data and the second instrument positional data to generate relative position data indicative of the relative position of the first surgical instrument with respect to the second surgical instrument.

(ORIGINAL) 71. The surgical telemetry system of claim 70, wherein the computer system is further configured to generate at least one of audio and visual feedback of the relative position data.

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(ORIGINAL) 72. The surgical telemetry system of claim 71, wherein:
the first surgical instrument is taken from a group consisting of an insertion device, an extraction device, an impacting device, a positioning device, a surgical reamer, a surgical saw, a cutting jig, a surgical drill, a hole-starter, a surgical screw, a surgical bolt, a surgical screw-driver, a surgical bolt-driver and a material applicator; and
the second surgical instrument is taken from a group consisting of a reference component; an insertion device, an extraction device, an impacting device, a positioning device, a surgical reamer, a surgical saw, a cutting jig, a surgical drill, a hole-starter, a surgical screw, a surgical bolt, a surgical screw-driver, a surgical bolt-driver and a material applicator.

(ORIGINAL) 73. The surgical telemetry system of claim 69, wherein:
the first surgical instrument is taken from a group consisting of an insertion device, an extraction device, an impacting device, a positioning device, a surgical reamer, a surgical saw, a cutting jig, a surgical drill, a hole-starter, a surgical screw, a surgical bolt, a surgical screw-driver, a surgical bolt-driver and a material applicator; and
the second surgical instrument is taken from a group consisting of a reference component; an insertion device, an extraction device, an impacting device, a positioning device, a surgical reamer, a surgical saw, a cutting jig, a surgical drill, a hole-starter, a surgical screw, a surgical bolt, a surgical screw-driver, a surgical bolt-driver and a material applicator.

(ORIGINAL) 74. A surgical telemetry system comprising:
a computer system having signal conditioning hardware and software;
a field generating device generating a detectable field approximate a reference object; and
at least one of a surgical instrument and a prosthetic component having a sensor carried thereon for sensing the detectable field, the sensor being operatively

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coupled to the signal conditioning hardware and software of the computer system to transmit positional data thereto relative to the detectable field.

(WITHDRAWN) 75. The surgical telemetry system of claim 74, wherein the sensor is a magnetometer and the field generator is at least one magnet.

(WITHDRAWN) 76. The surgical telemetry system of claim 75, wherein the field generator is a plurality of magnets adapted to be positioned about a circumference of a patient's acetabulum.

(WITHDRAWN) 77. The surgical telemetry system of claim 74, wherein the field generator is adapted to be mounted within a patient's anatomy.

(WITHDRAWN) 78. The surgical telemetry system of claim 74, wherein the field generator is mounted to an implantable component.

(WITHDRAWN) 79. The surgical telemetry system of claim 74, wherein the computer system is further configured to generate at least one of audio and visual feedback of the positional data.

(WITHDRAWN) 80. A surgical telemetry system comprising:
a sensor mounted to a prosthetic trial, the sensor including at least one of an accelerometer, a magnetometer, a gyroscope, and an inclinometer; and
a wireless transmitter operatively coupled to the sensor to disseminate broadcast data derived from output data attributable to the sensor.

(WITHDRAWN) 81. A surgical telemetry system comprising:
a sensor mounted to a prosthetic component, the sensor including at least one of an accelerometer, a magnetometer, a gyroscope, and an inclinometer; and

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a wireless transmitter operatively coupled to the sensor to disseminate broadcast data derived from output data attributable to the sensor.

(WITHDRAWN) 82. A surgical telemetry system comprising:

a sensor mounted to a surgical jig, the sensor including at least one of an accelerometer, a magnetometer, a gyroscope, and an inclinometer; and

a wireless transmitter operatively coupled to the sensor to disseminate broadcast data derived from output data attributable to the sensor.

(ORIGINAL) 83. A surgical telemetry system comprising:

a sensor mounted to a surgical device, the sensor including at least one of an accelerometer, a magnetometer, a gyroscope, and an inclinometer; and

a wireless transmitter operatively coupled to the sensor to disseminate broadcast data derived from output data attributable to the sensor;

wherein the surgical device is utilized in at least one of a total knee arthroplasty procedure and a total hip arthroplasty procedure.

(WITHDRAWN) 84. A surgical telemetry system comprising:

a sensor mounted to a surgical implant, the sensor including at least one of an accelerometer, a magnetometer, a gyroscope, or an inclinometer;

a digital processing device operatively coupled to the sensor to receive data derived from data output from the sensor, the digital processing device generating a display output; and

a display operatively coupled to the digital processing device and adapted to receive the display output, where the display output displays the change in at least one of position and orientation of the sensor with respect to a point of reference.

(ORIGINAL) 85. A surgical telemetry system comprising:

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a surgical instrument having an instrument positional sensor associated therewith, the instrument positional sensor coupled to a wireless transmitter to transmit output data from the instrument positional sensor indicative of the position of the surgical instrument;

an implantable prosthetic device having a prosthetic device positional sensor associated therewith, the prosthetic device positional sensor coupled to a wireless transmitter to transmit output data from the prosthetic device positional sensor indicative of the position of the implantable prosthetic device;

a surgical jig having a jig positional sensor associated therewith, the jig positional sensor coupled to a wireless transmitter to transmit output data from the jig positional sensor indicative of the position of the surgical jig;

an anatomical positional sensor adapted to be mounted to an anatomical feature of a patient, the anatomical positional sensor coupled to a wireless transmitter to transmit output data from the anatomical positional sensor indicative of the position of the anatomical feature; and

a data processing device comprising:

a receiver adapted to receive the transmitted output data,

processing circuitry to transform the transmitted output data,

a digital device operatively coupled to the processing circuitry including software operative to convert transformed sensor output data into relative position data adapted to be viewable to reflect at least one of position and orientation of at least one of the surgical instrument, the implantable prosthetic device, the surgical jig, and the anatomical positional sensor, and

a visual display for viewing the relative position data.

(ORIGINAL) 86. A method of supplementing a surgical procedure using a surgical telemetry system comprising:

using a surgical device including a sensor mounted thereto, the sensor taken from the group consisting of an accelerometer, a magnetometer, a gyroscope, or an inclinometer, and the surgical device taken from the group consisting of a surgical instrument, a prosthesis or a surgical jig;

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operatively coupling the sensor of the surgical device to at least one of a wired receiver and a wireless receiver to receive output data generated by the sensor indicative of at least one of position data and orientation data; and
generating feedback data derived from the output data of the sensor.

(ORIGINAL) 87. A method of manufacturing a medical device, the method comprising the steps of:
associating at least one of an accelerometer, a gyroscope, a magnetometer, and an inclinometer with a medical device; and
associating a wireless transmitter with at least one of an accelerometer, a gyroscope, a magnetometer, and an inclinometer, where the wireless transmitter is adapted to transmit wireless data derived from output data from at least one of the accelerometer, the gyroscope, the magnetometer, and the inclinometer.

(WITHDRAWN) 88. A method of manufacturing a prosthetic device, the method comprising the steps of:
associating at least one of an accelerometer, a gyroscope, a magnetometer, and an inclinometer with a prosthetic device; and
associating a wireless transmitter with at least one of an accelerometer, a gyroscope, a magnetometer, and an inclinometer, where the wireless transmitter is adapted to transmit wireless data derived from output data from at least one of the accelerometer, the gyroscope, the magnetometer, and the inclinometer.

(ORIGINAL) 89. A method of generating telemetry data regarding the position of an object during a surgical procedure, the method comprising the steps of:
receiving a transmission from a transmitter operatively coupled to at least one of an accelerometer, a gyroscope, a magnetometer, and an inclinometer associated with at least one of a medical device and a prosthetic device adapted for use with a surgical procedure;

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processing the transmission from the transmitter into a format amendable to visual display; and

displaying the format onto the visual display such that changes in position of at least one of the medical device and the prosthetic device are reflected in substantially real-time and correspond substantially to an actual position of at least one of the medical device and the prosthetic device.

(ORIGINAL) 90. A method of manufacturing a surgical device, the method comprising the steps of:

associating at least one of an accelerometer, a gyroscope, a magnetometer, and an inclinometer with a surgical device; and

associating a wireless transmitter with at least one of the accelerometer, the gyroscope, the magnetometer, and the inclinometer, where the wireless transmitter is adapted to transmit wireless data derived from output data from at least one of the accelerometer, the gyroscope, the magnetometer, and the inclinometer.

(ORIGINAL) 91. A method of generating telemetry data regarding the position of an object during a surgical procedure, the method comprising the steps of:

receiving a transmission from a transmitter operatively coupled to at least one of an accelerometer, a gyroscope, a magnetometer, and an inclinometer associated with at least one of a surgical device, an implant, and a prosthetic component adapted for use with a surgical procedure;

processing the transmission from the transmitter into a format amendable to visual display; and

displaying the format onto a visual display such that changes in position of at least one of the medical device and the prosthetic device are reflected in substantially real-time and correspond substantially to an actual position of at least one of the medical device and the prosthetic device.